

CLAIMS

1. A method, comprising:

5 applying to a localized region of a body of a patient a binding partner immobilized relative to or able to be immobilized relative to a signaling entity; and determining immobilization of the signaling entity within or on the body of the patient.

10 2. A method, comprising:

applying to a body of a patient a binding partner immobilized relative to or able to be immobilized relative to a signaling entity, wherein the signaling entity is able to enhance an optical contrast of a tissue of the body to which it becomes immobilized; and optically determining immobilization of the signaling entity to the tissue.

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3. A kit, comprising:

at least one of a signaling entity and a binding partner capable of being immobilized relative to the signaling entity; and instructions directing a user to immobilize the signaling entity relative to the binding partner, to apply the binding partner and signaling entity to a localized region of a body of a patient, and to determine immobilization of the signaling entity within or on the body of the patient.

25 4. A kit, comprising:

an article comprising a signaling entity and a binding partner immobilized relative to the signaling entity; and instructions directing a user to apply the article to a localized region of a body of a patient, and to determine immobilization of the article within or on the body of the patient.

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5. A method, comprising:

promoting the application to a localized region of a body of a patient of a binding

partner immobilized relative to or able to be immobilized relative to a signaling entity, and the determination of immobilization of the signaling entity within or on the body of the patient.

- 5 6. A method or a kit as in any preceding claim, wherein the patient is a human.
7. A method as in claims 1 or 2, wherein the patient is undergoing a surgical procedure.
8. A method or a kit as in any preceding claim, wherein the localized region is a surgical
10 field.
9. A method or a kit as in any preceding claim, wherein the localized region comprises a region of the skin of the patient.
- 15 10. A method as in claim 7, wherein the surgical procedure is a minimally-invasive procedure.
11. A method as in claim 7, wherein the surgical procedure is an endoscopic or laproscopic procedure.
- 20 12. A method as in claim 7, wherein the surgical procedure involves removal of a diseased tissue.
13. A method as in claim 12, wherein the diseased tissue comprises a cancerous cell.
- 25 14. A method as in claim 12, wherein the diseased tissue comprises a tumor.
15. A method as in claim 12, wherein the binding partner is specific for a species on the diseased tissue.

16. A method as in claim 12, wherein a signaling entity or a colloid particle is immobilized to or able to become immobilized to the diseased tissue.
- 5 17. A method as in claims 16, further comprising the step of removing a portion of diseased tissue from the body of the patient before the applying step.
18. A method as in claim 17, further comprising the step of removing any tissue or cells to which the signaling entity or colloid particle is immobilized.
- 10 19. A method as in claim 18, wherein the removing of any tissue or cells to which the signaling entity or colloid particle is immobilized occurs after the determining step.
20. A method as in claim 7, wherein the surgical procedure occurs on the face of the patient.
- 15 21. A method as in claim 7, wherein the surgical procedure is localized to a specific organ.
22. A method or a kit as in any of claims 1-6, wherein the binding partner is a biological binding partner.
- 20 23. A method or a kit as in any of claims 1-6, wherein the binding partner is a protein.
24. A method or a kit as in any of claims 1-6, wherein the binding partner is an antibody.
- 25 25. A method or a kit as in any of claims 1-6, wherein the binding partner is an enzyme.
26. A method or a kit as in any of claims 1-6, wherein the binding partner is a nucleic acid.
27. A method or a kit as in any of claims 1-6, wherein the binding partner is a peptide.
- 30 28. A method or a kit as in any of claims 1-6, wherein the signaling entity is identifiable or able to become identifiable by the unaided human eye.

29. A method or a kit as in any of claim 1-6, wherein the signaling entity is able to absorb or emit electromagnetic radiation.
- 5 30. A method or a kit as in any of claims 1-6, wherein the signaling entity is electronically detectable.
31. A method or a kit as in any of claims 1-6, wherein the signaling entity is chemically detectable.
- 10 32. A method or a kit as in claim 29, wherein the signaling entity is fluorescent.
33. A method or a kit as in claim 29, wherein the signaling entity is chemiluminescent.
- 15 34. A method or a kit as in any of claims 1-6, wherein the signaling entity is a colloid particle.
35. A method or a kit as in any of claims 1-6, wherein the binding partner is fastened to the signaling entity.
- 20 36. A method or a kit as in any of claims 1-6, wherein the binding partner is fastened to a component to which the signaling entity is fastened.
37. A method or a kit as in claim 36, wherein the component is a colloid particle.
- 25 38. A method as in claims 1 or 2, wherein the determining step comprises electrically detecting the signaling entity.
39. A method as in claims 1 or 2, wherein the determining step comprises optically detecting the signaling entity.

40. A method as in claim 39, wherein the determining step comprises spectroscopically detecting the signaling entity.
41. A method as in claim 39, wherein the determining step comprises visually detecting the 5 signaling entity.
42. A method as in claims 1 or 2, wherein the determining step comprises determining a concentration of signaling entity within or on the body of the patient.
- 10 43. A method as in claims 1 or 2, wherein the determining step comprises determining a location or a pattern of immobilization of the signaling entity within or on the body of the patient.
- 15 44. A method, comprising:
 - allowing a colloid particle the ability to fasten to a localized region of a body of a patient; and
 - determining fastening of the colloid particle within or on the body of the patient.
45. A method, comprising:
 - allowing a colloid particle the ability to fasten to a body of a patient, wherein the colloid particle is capable of enhancing the optical contrast of a tissue of the body to which it becomes fastened; and
 - optically determining fastening of the colloid particle to the tissue.
- 25 46. A kit, comprising:
 - a colloid particle; and
 - instructions directing a user to apply the colloid particle to a localized region of a body of a patient, and to determine fastening of the colloid particle within or on the body of the patient.

47. A method, comprising:

promoting the application to a localized region of a body of a patient of a colloid particle, and the determination of fastening of the colloid particle within or on the body of the patient.

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48. A method or a kit as in any of claims 44-47, wherein the patient is a human.

49. A method claim 44 or 45, wherein the patient is undergoing a surgical procedure.

10 50. A method or a kit as in any of claims 44-49, wherein the localized region is a surgical field.

51. A method or a kit as in any of claims 44-50, wherein the localized region comprises a region of the skin of the patient.

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52. A method as in claim 49, wherein the surgical procedure is a minimally-invasive procedure.

20 53. A method as in claim 49, wherein the surgical procedure is an endoscopic or laproscopic procedure.

54. A method as in claim 49, wherein the surgical procedure involves removal of a diseased tissue.

25 55. A method as in claim 54, wherein the diseased tissue comprises a cancerous cell.

56. A method as in claim 54, wherein the diseased tissue comprises a tumor.

20 57. A method as in claim 54, wherein the colloid particle is immobilized to or is able to become immobilized to the diseased tissue.

58. A method as in claim 57, further comprising the step of removing any tissue or cells to which the colloid particle is immobilized to.
- 5 59. A method as in claim 49, wherein the surgical procedure occurs on the face of the patient.
60. A method as in claim 49, wherein the surgical procedure is localized to a specific organ.
- 10 61. A method as in claims 44 or 45, wherein the determining step comprises optically detecting the colloid particle.
62. A method as in claim 61, wherein the determining step comprises spectroscopically detecting the signaling entity.
- 15 63. A method as in claim 61, wherein the determining step comprises visually detecting the signaling entity.
64. A method as in claims 44 or 45, wherein the determining step comprises determining a concentration of the colloid particle within or on the body of the patient.
- 20 65. A method as in claims 44 or 45, wherein the determining step comprises determining the location or pattern of immobilization of the colloid particle within or on the body of the patient.
- 25 66. A method or kit as in claims 44-48, wherein at least one signaling entity is fastened to the colloid particle.
67. A method or a kit as in claims 44-48 wherein the colloid particle itself acts as a signaling entity.

68. A method or a kit as in claims 44-48 wherein an agglomeration of colloid particles acts as a signaling entity.
69. A method or a kit as in claim 68, wherein the colloid particles agglomerate on a specific target in the localized region of the body.
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70. A method, comprising:
 - exposing at least a portion of a biological sample derived from a patient indicated for treatment for, or at risk of acquiring, a medical condition to a first therapeutic protocol known to have efficacy for treating or preventing the condition;
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 - determining a response of the biological sample indicative of the effectiveness of the first therapeutic protocol in treatment or prevention of the condition.
71. A method as in claim 70, further comprising the step of exposing at least a portion of the biological sample to a second therapeutic protocol known to have efficacy for treating or preventing the condition.
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72. A method as in claim 71, further comprising the step of determining a response of the biological sample indicative of the effectiveness of the second therapeutic protocol in treatment or prevention of the condition.
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73. A method as in claim 72, further comprising the step of treating the patient according to either the first or second therapeutic protocols based the results of the determining steps.
74. A method as in any of claims 70-73, wherein the patient is a human.
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75. A method as in any of claims 70-74, wherein the biological sample comprises at least one cell.
76. A method as in any of claims 70-74, wherein the biological sample comprises a cell culture expanded from a precursor sample taken from the patient.
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77. A method as in any of claims 70-74, wherein the biological sample comprises a tissue.
78. A method as in any of claims 70-74, wherein the biological sample comprises biological fluid.
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79. A method as in any of claims 70-74, wherein the biological sample comprises a protein, peptide, or a nucleic acid.
- 10 80. A method as in claim 79, wherein the protein, peptide, or a nucleic acid has a sequence or structure essentially identical to a corresponding protein, peptide, or nucleic acid of the patient.
- 15 81. A method as claim 80, wherein the protein, peptide, or nucleic acid having a sequence or structure essentially identical to a corresponding protein, peptide, or nucleic acid of the patient is a synthetic protein, peptide, or a nucleic acid.
82. A method as in any of claims 79-81, wherein the protein, peptide, or nucleic acid is immobilized relative to a surface of solid support.
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83. A method as in claim 82, wherein the solid support is a colloid.
84. A method as in any of claims 70-74, wherein the biological sample comprises blood or a blood-derived component.
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85. A method as in any of claims 70-74, wherein the biological sample comprises an antibody.
86. A method as in claim 85, wherein the antibody has a specificity for a material administered as at least a part of the therapeutic protocol.
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87. A method as in any of claims 70-74, wherein the first therapeutic protocol comprises administering a candidate drug.
88. A method as in any of claims 70-74, wherein the first therapeutic protocol comprises administering a protein.
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89. A method as in any of claims 70-74, wherein at least one determining step involves a binding assay employing a colloid particle.
- 10 90. A method as in claim 89, wherein the colloid particle is immobilized or able to be immobilized to a binding partner.
91. A method as in claim 90, wherein the binding partner is specific for at least one species contained in the biological sample.
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92. A method as in claim 90, wherein the binding partner comprises at least one species contained in the biological sample.
93. A method as in claim 90, wherein at least one determining step comprises determining binding of a ligand to the binding partner in the presence of a drug agent.
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94. A method as in claim 90, wherein the binding partner is an antibody.
95. A method as in claim 90, wherein the binding partner is an enzyme.
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96. A method as in claim 90, wherein the binding partner is a nucleic acid.
97. A method as in claim 90, wherein the binding partner is a peptide.
- 30 98. A method as in claim 90, wherein the binding partner is immobilized relative to or able to be immobilized relative to a signaling entity.

99. A method as in claim 98, wherein the binding partner is fastened to the signaling entity.
100. A method as in claim 98, wherein the binding partner is fastened to a component to
5 which the signaling entity is fastened.
101. A method as in claim 98, wherein the signaling entity is identifiable by the unaided
human eye.
- 10 102. A method as in claim 98, wherein the signaling entity is able to absorb or emit
electromagnetic radiation.
103. A method as in claims 98, wherein the signaling entity is the colloid particle.
- 15 104. A method as in any of claims 70-74, wherein at least one exposing step comprises
exposing the at least a portion of the biological sample to a binding partner able to bind
to at least one species in the sample.
105. A method as in any of claims 71-73, wherein the exposing steps are simultaneously
20 performed.
106. A method as in any of claims 70-74, wherein at least one determining step comprises
determining an efficacy of at least one of the therapeutic protocols.
- 25 107. A method as in any of claims 70-74, wherein at least one determining step comprises
detecting binding of a ligand to at least one species present in the biological sample.
108. A method as in any of claims 70-74, wherein at least one determining step comprises
determining a signaling entity concentration.

109. A method as in any of claims 70-74, wherein at least one determining step comprises determining a presence, concentration, or distribution of a protein or a peptide in the biological sample.
- 5 110. A method as in any of claims 70-74, wherein at least one determining step comprises detecting a signaling entity.
111. A method as in any of claims 70-74, wherein at least one determining step comprises optically detecting a signaling entity.
- 10 112. A method as in any of claims 70-74, wherein at least one determining step comprises detecting electromagnetic radiation from the sample.
113. A method as in any of claims 70-74, wherein the medical condition is cancer.
- 15 114. A method as in any of claims 70-74, wherein the medical condition is a disease other than cancer.